

(3) The ingredient is used as a stabilizer and thickener as defined in §170.3(o)(28) of this chapter in peanut butter. The use level of the ingredient is limited by good manufacturing practice (GMP) to the minimum amount required to produce the intended effect. Current good manufacturing practices result in a maximum level of 2 percent in peanut butter.

(b) *Superglycerinated fully hydrogenated rapeseed oil.* (1) Superglycerinated fully hydrogenated rapeseed oil is a mixture of mono- and diglycerides with triglycerides as a minor component. The fatty acid composition is a mixture of saturated fatty acids present in the same proportions as those resulting from the full hydrogenation of fatty acids in natural rapeseed oil. It is made by adding excess glycerol to the fully hydrogenated rapeseed oil and heating, in the presence of a sodium hydroxide catalyst, to 330 °F under partial vacuum and steam sparging agitation.

(2) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 201, relating to mono- and diglycerides, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408. An additional specification requires the iodine number to be 4 or less.

(3) The ingredient is used as an emulsifier as defined in §170.3(o)(8) of this chapter in shortenings for cake mixes. The use level of the ingredient is limited by good manufacturing practice (GMP) to the minimum amount required to produce the intended effect. Current good manufacturing practices result in a maximum level, as served, of 4 percent of the shortening or 0.5 percent of the total weight of the cake mix.

(c) *Low erucic acid rapeseed oil.* (1) Low erucic acid rapeseed oil, also known as canola oil, is the fully refined, bleached, and deodorized edible oil obtained from certain varieties of *Brassica Napus* or *B. Campestris* of the family *Cruciferae*. The plant varieties are those producing oil-bearing seeds

with a low erucic acid content. Chemically, low erucic acid rapeseed oil is a mixture of triglycerides, composed of both saturated and unsaturated fatty acids, with an erucic acid content of no more than 2 percent of the component fatty acids.

(2) Low erucic acid rapeseed oil as defined in paragraph (c)(1) of this section may be partially hydrogenated to reduce the proportion of unsaturated fatty acids. When the partially hydrogenated low erucic acid rapeseed oil is used, it shall be referred to as partially hydrogenated low erucic acid rapeseed oil.

(3) In addition to limiting the content of erucic acid to a level not exceeding 2 percent of the component fatty acids, FDA is developing other food-grade specifications for low erucic acid rapeseed oil and partially hydrogenated low erucic acid rapeseed oil in cooperation with the National Academy of Sciences. In the interim, the ingredients must be of a purity suitable for their intended use.

(4) Low erucic acid rapeseed oil and partially hydrogenated low erucic acid rapeseed oil are used as edible fats and oils in food, except in infant formula, at levels not to exceed current good manufacturing practice.

[42 FR 48336, Sept. 23, 1977, as amended at 49 FR 5613, Feb. 14, 1984; 50 FR 3755, Jan. 28, 1985; 53 FR 52682, Dec. 29, 1988]

#### § 184.1560 Ox bile extract.

(a) Ox bile extract (CAS Reg. No. 8008-63-7), also known as purified oxgall or sodium choleate, is a yellowish green, soft solid, with a partly sweet, partly bitter, disagreeable taste. It is the purified portion of the bile of an ox obtained by evaporating the alcohol extract of concentrated bile.

(b) Food-grade ox bile extract shall meet the specifications of the U.S. Pharmacopeia (USP), XIV, 1950, p. 410.<sup>1</sup>

(c) The ingredient is used as a surfactant as defined in §170.3 (o)(29) of this chapter.

(d) The ingredient is used in food in accordance with §184.1(b)(1) at levels not to exceed good manufacturing

<sup>1</sup>Copies may be obtained from: U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

practice. Current good manufacturing practice results in a maximum level, as served, of 0.002 percent for cheese as defined in § 170.3(n)(5) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 36064, Aug. 15, 1978. Redesignated and amended at 50 FR 49537, Dec. 3, 1985]

**§ 184.1563 Ozone.**

(a) Ozone (O<sub>3</sub>, CAS Reg. No. 10028-15-6) is an unstable blue gas with a pungent, characteristic odor, which occurs freely in nature. It is produced commercially by passing electrical discharges or ionizing radiation through air or oxygen.

(b) The ingredient must be of a purity suitable for its intended use in accordance with § 170.30(h)(1) of this chapter.

(c) In accordance with § 184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

Category of food	Maximum treatment level in food	Functional use
Bottled water that prior to ozonation meets the microbiological, physical, chemical, and radiological quality standards of § 165.110 (b)(2) through (b)(5) of this chapter.	Not to exceed current good manufacturing practice. Current good manufacturing practice results in a maximum residual level at the time of bottling of 0.4 milligram of ozone per liter of bottled water.	Antimicrobial agent, § 170.3 (o)(2) of this chapter.

[47 FR 50210, Nov. 5, 1982, as amended at 60 FR 57130, Nov. 13, 1995]

**§ 184.1583 Pancreatin.**

(a) Pancreatin (CAS Reg. No. 8049-47-6) is an enzyme preparation obtained from porcine or bovine pancreatic tissue. It is a white to tan powder. Its characterizing enzyme activity that of a peptide hydrolase (EC 3.4.21.36).

(b) The ingredient meets the general requirements and additional requirements in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Acad-

emy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995]

**§ 184.1585 Papain.**

(a) Papain (CAS Reg. No. 9001-73-4) is a proteolytic enzyme derived from *Carica papaya* L. Crude latex containing the enzyme is collected from slashed unripe papaya. The food-grade product is obtained by repeated filtration of the crude latex or an aqueous solution of latex or by precipitation from an aqueous solution of latex. The resulting enzyme preparation may be used in a liquid or dry form.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 107-110, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter; processing aid as defined in